The Effect of Warm Foot Bath and Massage on Selected Hemodynamic Parameters among Patients with Traumatic Brain Injury: Randomized Clinical Trial

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Abstract

Background: Head trauma can cause decreased consciousness levels and reduced ability to respond to the environment, leading to impaired cognitive, perceptual, and sensory functions in people. One of the techniques that can help improve brain function is a warm bath. **Aim of the study:** the aim of the current study is to determine the effect of warm foot bath & massage on selected hemodynamic parameters among patients with traumatic brain injury. **Research Design:** Randomized clinical trial research design was utilized in this study. **Setting:** the current study was carried out at the neurological ICU in Ain Shams University Hospitals. **Sample:** a purposive sample according to the inclusion criteria over three months, was randomly assigned to the study group (30) patients, and control group (30) patients. **Tools of data collection:** Two tools were utilized to collect data pertinent to the current study: **tool (I)**: patient's demographic and medical data sheet, **tool (II)**: warm foot bath & massage assessment checklist. **Results:** the Glasgow Coma Scale of the study group is significantly less than the mean GCS of the control group at all times of day 1 and day 2 and also before intervention and after 1 hour on day 3 and before intervention on day 4 and the mean of the study group was improved at the last days than the first days, there is a significant difference within times of each group. The mean temperature of the study group is significantly less than the mean of the control group after 3 hours on day 4. The mean pulse of the study group is significantly higher than the mean of the control group before intervention and after 1 hour on day 3 and before intervention on day 4. There is a significant difference within times of each group. The mean respiratory rate of the study group is significantly higher than the mean of the control group before intervention and after 3 hours on day 3. There is no significant difference between mean systolic blood pressure of the study the control groups at any time. There is no significant difference between mean diastolic blood pressure of the study and control groups at any time. The mean of oxygen saturation of the study group is significantly higher than the mean of the control group. **Conclusion:** warm foot bath & massage can improve the GCS, respiratory rate, and oxygen saturation among patients with traumatic brain injury for the study group. **Recommendations:** Based upon the findings of the study, the following are recommended: applying the warm foot bath & massage for patients with traumatic brain injury, replication of the same study on larger probability samples at different geographical locations for data generalization.

Keywords: Warm Foot Bath, Massage, Hemodynamic Parameters, Traumatic Brain Injury, Randomized Clinical Trial

Introduction

Traumatic brain injury (TBI), which affects a lot of people in a lot of different demographics, is one of the largest problems in the world **(Algattas & Huang, 2014).** Traumatic head injury (THI) is the term for damage to the scalp, skull, or brain. These injuries can range in severity from a minor skull bump to TBI, among others **(Sole, Klein, & Moseley, 2013).**TBI can come from disturbance of brain activity brought on by an external force or hard hit to the head, which can have both immediate and more long-lasting effects on patients. TBI can also increase long-term mortality and result in persistent disability **(Silver, McAllister, 2018; Obenaus, 2016).** Additionally, it may result in a number of behaviora, social, emotional, cognitive, and social deficits **(Bajwa, Kesavan, & Mohan, 2018).**

Additionally, head trauma can cause a number of secondary pathological illnesses, such as seizures, sleep issues, neurodegenerative diseases, dysregulation of the neuroendocrine system, mental issues, changes in the state of consciousness, and numerous other issues **(Mahmoodi, 2013).** As **Brenner has shown (2012),** two of the main causes of subsequent brain injury in TBI are hypoxia and hypoperfusion. According to one study, people with severe TBI who experienced two or more episodes of hypotension were two to eight times more likely to pass away. It has also been discovered that hypotension within the first 48 hours after ICU admission is a predictor of mortality. Patients with severe TBI require close observation in a neurologic ICU so they can receive care to lessen the risk of sustaining additional brain damage.

Hydrotherapy is recognized as having a high therapeutic impact in conventional and complementary medicine since it is widely applicable to patient care and rehabilitation. One of the most important interventions and therapeutic approaches that maximizes the features and advantages of water is this one **(Mooventhan & Nivethitha, 2014).** Hydrotherapy is a discipline that aims to improve health or treat disease by using various therapeutic characteristics of water. Hydrotherapy is frequently used as a local cold or heat therapy in the medical industry, and it has been proven to be particularly beneficial in easing musculoskeletal problems and accelerating the healing process following injuries **(An, Lee, & Yi, 2019).**

Hydrotherapy typically has thermal, mechanical, and chemical side effects, either by themselves or in combination. Heat (35–40 °C), body temperature (32–34 °C), or cold (8–10 °C) therapy all produce thermal effects. While cold therapy is often described by vasoconstriction and pain-relieving benefits, heat therapy is typically explained by vasodilation and blood flow facilitation effects **(An, Lee, & Yi, 2019).**

There are many different physiological impacts and therapeutic uses for hydrotherapy. The increased blood flow caused by using water of varied temperatures is supposed to aid in the removal of all toxins and promote muscular relaxation. Additionally, by lowering peripheral edema and calming down sympathetic nervous system activity, the hydrostatic impact may reduce pain **(Mooventhan & Nivethitha, 2014).** Hydrotherapy has been the subject of substantial research and has emerged as an effective intervention for the treatment of a number of systemic illnesses. Numerous therapies can be carried out at home, which lowers their cost and involves the patient more actively **(Dhananjay and Jincy, 2012).** Furthermore, **Wijayanto et al. (2013)** have shown that warm water immersion therapy can increase blood flow rate, which in turn can enhance the movement of substances in the blood and enhance the function of vital organs like the brain.

The use of massage treatment, which dates back thousands of years, is a widespread healing practice. Numerous clinical trials have been conducted as a result of recent interest in the role of massage therapy as an adjunct to traditional medical therapy, and many of these have demonstrated improvements in hemodynamic and nervous system functions. The effects of massage include feelings of warmth, relaxation, and wellbeing.

It is crucial for nurses to have a valuable resource with evidence-based recommendations on nursing activities in order to help them achieve the best results possible. Nurses are the health professionals who see the full impact of TBI and have the skills that can change a patient's course of recovery. To give persons with TBI the care they need, nurses need the necessary knowledge and abilities. They are therefore essential to the care of those patients **(Varghese, Chakrabarty, & Menon, 2017).** Furthermore, there are overlaps between nursing and medical management because nurses working in intensive care units (ICUs) are in charge of maintaining patients' physiological, psychological, and emotional needs as well as monitoring these needs on a constant basis **(Seliman, Morsy, Sultan, Elshamy, & Ahmed, 2014).**

Furthermore, nursing responsibilities in TBI include monitoring patient hemodynamic stability, performing serial neurological examinations, and preventing secondary injury. Therefore, the present study aimed to determine the effect of warm foot bath on the level of consciousness and selected hemodynamic parameters in patients with traumatic brain injury.

Significance of the Study

In the United States, TBI from head trauma frequently presents in emergency rooms and is responsible for over a million visits each year TBI is the leading cause of disability in children and adults and a major cause of mortality and morbidity globally **(Shaikh & Waseem, 2021).** According to recent data, there were 10729 head trauma deaths in Egypt in 2010, or 13.2 per 100,000 people, mostly as a result of motor vehicle accidents **(WHO, 2010).**

TBI has a significant impact on the patients and their family. In addition, a sizable percentage of survivors need hospital care, prolonged rehabilitation, and may have long-term physical, cognitive, and psychological disorders. Cognitive deficits brought on by TBI interfere with work, relationships, leisure, and activities of daily living, exacting a personal and economic cost that is challenging to quantify. Head trauma can result in loss of consciousness and a diminished capacity to react to the environment, impairing cognitive, perceptual, and sensory abilities in the victims. After an injury, these consequences may continue for months or even years, greatly affecting the patient's' quality of life **(Rabinowitz & Levin, 2014).**

With varying degrees of effectiveness, studies have looked at several therapy approaches to address both the acute and long-term effects of TBI (**Bramlett & Dietrich, 2015).** However, taking a warm bath is one method that can aid in these situations to boost brain function **(Azimain, et al, 2020).** According to **Bunt et al. (2016),** warm water immersion may slow the development of vascular pathologic alterations like atherosclerosis. Furthermore, warm water immersion boosted levels of chemicals involved in brain-cell genesis, which helped to improve tissue oxygenation and short-term brain function. The blood flow is increased through vasodilatation, according to **Kumar (2020),** by raising the temperature of the skin and soft tissues. Heat also accelerates tissue healing and boosts oxygen intake, as well as the metabolic rate and tissue extensibility. It also stimulates the activity of enzymatic breakers like collagenase and speeds up the catabolic rate.

Theoretical Framework

The theoretical framework for the current study was Nursing Process. The definition of the nursing process is a systematic, logical planning approach that directs all nursing actions in providing all-encompassing, patient-focused care. In order to give the patient the greatest care possible, the nursing process, which is a type of scientific reasoning, calls for the nurse to use critical thinking. With five consecutive steps, the nursing process serves as a structured manual for client-centered care. These include evaluation, planning, implementation, diagnosis, and assessment **(Wayne, 2022).** So, the nursing process in this study is used as a theoretical framework in which the elements of nursing process and steps of nursing process are matched with the current study. At first, we started with the assessment of patients to ensure patient's inclusion criteria. Second; planning for the study implementation through preparation data collection tools, then providing the individualized nursing interventions which include foot warm bath and massage, then evaluating the effect of warm bath and massage on the patient's level of consciousness, vital signs, and oxygen saturation.

Theoretical definition:

Hemodynamic parameters: are parameters that are used to assess the patient's health status, as they may significantly affect can facilitate clinical decision-making, allow customization of a treatment plan, they include heart rate and blood pressure, mean pulmonary artery pressure and cardiac output …ect **(Brunner, 2018).**

- **Traumatic brain injury (TBI),** a form of acquired brain injury, occurs when a sudden trauma causes damage to the brain. TBI can result when the head suddenly and violently hits an object **(NINDS, 2022).**
- **Warm foot bath (HFB)** consists of placing the feet in hot water for specific health outcome by **(Sigh & Hall, 2020).**
- **Massage** therapy is the practice of rubbing or manipulating a person's muscles and other soft-tissue in order to improve their wellbeing or health **(Stuart, 2020).**

Operational definition:

- **Selected hemodynamic parameters**: It refers to the parameters that assessed in the current study which include the level of consciousness that measured by Glasgow coma scale, checking the vital signs and the oxygen saturation.
- **Traumatic brain injury (TBI):** Patients with head trauma who have a level of consciousness between 6 and 12 Patients as assessed by Glasgow coma scale.
- **Warm foot bath (HFB):** The immersion of the ankle to toes in warm water with temperature of (40-42ºC) which measured by Celsius thermometer, and evaluated for its effect by warm foot bath & massage assessment checklist (tool 2).
- **Massage:** Is performing of general foot rubbing by putting four fingers on the dorsal aspect of the patient's foot and using the thumb to make rotational pressure on the sole, and evaluated for its effect by warm foot bath & massage assessment checklist (tool 2).

Aim of the study

The aim of the study is to determine the effect of warm foot bath & massage on selected hemodynamic parameters among patients with traumatic brain injury.

Research hypothesis

To achieve the aim of the present study, the following null hypothesis was formulated:

H1: There is no difference in the level of consciousness, vital signs, and oxygen saturation between patients who will receive warm foot bath & massage and patients who won't.

Subjects and Methods

Research Design: Randomized clinical trial research design was utilized in this study.

Sample: The current study included a purposive sample according the inclusion criteria over three months, and was randomly assigned to the study group (30) patients, and control group (30) patients.

Inclusion criteria: Patients with head trauma, based on the GCS, a level of consciousness between 6 and 12 patients, both genders, age between 18- and 65-years, within 3 days post admission.

Exclusion criteria: are as follows: The presence of fractures, ulcers, infections and skin disease in the wrist to the extremities of both fingers, limitation of movement of the lower limbs, Lower limb amputees' patients who have a history of coma in the past have a sensory and neurological disorder & patients more than 4 days post admission.

Setting: This study was carried out at the neurological ICU in Ain Shams University Hospitals.

Tools of data collection:

Two tools were utilized to collect data pertinent to the current study:

<u>Tool I:</u> Patient's Demographic and Medical Data Sheet:

It is developed by the researchers; it contains data related to patients such as code number, gender, age, medical diagnosis, main reason for ICU admission, co-morbidity diseases.

<u>Tool II:</u> Warm Foot Bath & Massage Assessment Checklist:

It is adopted and includes the Glasgow Coma Scale (GCS), vital signs, and oxygen saturation to assess effect of warm foot bath on those three selected hemodynamic parameters.

The Glasgow Coma Scale (GCS) was developed by neurosurgery professors Graham Teasdale and Bryan Jennett, in 1974 at the University of Glasgow. Glasgow Coma Scale (GCS) is a neurological scale aiming to provide a reliable, objective way of recording the conscious state of a person, both for initial and continuing assessment of the patient, which has a special value in predicting the ultimate outcome. Generally, comas are classified as: severe, with GCS ≤8, moderate, GCS 9–12, and minor, GCS ≥13.

GCS is the most common scoring system used to describe the level of consciousness in a person following a traumatic brain injury. Basically, it is used to help gauge the severity of an acute brain injury. The test is simple, reliable, and correlates well with outcome following severe brain injury. Every brain injury is different, but generally, brain injury is classified as:

- Severe: GCS 8 or less
- Moderate: GCS 9-12
- Mild: GCS 13-15

Tool's reliability:

In 171 patients who were receiving care in the neuro-intensive care unit, **Mayer et al. (2003)** looked at the internal consistency of the GCS. Excellent results were found for Cronbach's alpha (alpha = 0.83). In addition**,** **Gill, Reiley, and Green (2004)** looked at the inter-rater reliability of the GCS in 116 patients with varied diagnoses who visited the emergency room (10 of whom had a stroke, or 9% of the sample). Within five minutes of one another, two attending emergency physicians blinded to each other's scores independently evaluated the GCS. Kappa statistics were calculated for each of the GCS subtests and the total score. Best eye response had adequate inter-rater reliability (weighted k = 0.72) as did Best verbal response (weighted k = 0.48) and best motor response (weighted k = 0.40). The agreement percentage for total GCS was 32% (Kendall's T-b = 0.74; Spearman rho = 0.86; Spearman rho2 = 75%). Agreement percentage for GCS Best eye response was 74% (T-b = 0.72; Spearman rho = 0.76; Spearman rho2 = 57%), verbal 55% (T-b = 0.59; Spearman rho = 0.67; Spearman rho2 = 44%), and motor 72% (T-b = 0.74; Spearman rho = 0.81; Spearman rho2 = 65%).

Content validity

The content validity of the developed tools was tested through being reviewed by a panel of three experts in the field of critical care and emergency nursing in order to ensure content comprehensiveness, clarity, relevance, and applicability.

Procedure:

The current study was carried out through two phases: preparation and implementation.

1- **Preparation phase:**

Conduction of the current study started with extensive literature review, selection and preparation of the data collection tools.

2-**Implementation phase:**

An official approval granted from the Research Ethics Committee**,** Faculty of Nursing**,** Cairo University to proceed with the study. Official permission was obtained from the Manager of the selected ICU to precede the study. The purpose of the study was explained to the relatives of the patients and written consent was taken. The researchers assured the voluntary participation and confidentiality to each patient's relative who agreed to participate.

The researchers utilized the simple randomization methods in the current study, this technique maintains complete randomness of the assignment of a subject to a particular group. The researchers used flipping a coin as a method of simple randomization. This technique maintains complete randomness of the assignment of a patient to a particular group. The current study included a control group and a study group the side of the coin (heads =control, tails =intervention) determines the assignment of each patient (Figure- 1), Single blindness was applied in the current study which means that the research participants were not told of the treatment assignment.

The researchers visited the selected ICU on a daily base, the intervention was performed between 8.30 am to 1.30 pm, at the first, the researchers prepared the needed equipment (thermometer, a plastic basin, rubber sheet, towel, gloves). The patient's vital signs (systolic blood pressure (SBP), diastolic blood pressure (DBP), respiratory rate (RR), pulse rate (PR), oxygen saturation (SaO2), and GCS) immediately were checked before the intervention, then the researchers put the rubber sheet under the plastic basin to protect the bed linen. The warmed water was added into the plastic basin after measuring with the thermometer (40-42ºC), then, the researchers set the patient in a comfortable position and exposed the foot. The gloves were done and immersed the patient's foot (from the ankle to toes) in warm water then applied the foot massage which included a general foot rubbing by putting four fingers on the dorsal aspect of the patient's foot and using the thumb to make rotational pressure on the sole, once a day for 15 minutes for 7 consecutive days.

Upon completion of the intervention, the patient's foot was raised from the basin, and dry it's by a towel, then removed the plastic basin, and the rubber sheet, then the patient was covered again with the linen. At the end, the patient's GCS, vital signs, and oxygen saturation were checked for the second time after one hour, and the third time three hours after the intervention for seven days. No intervention was provided for the control group, they received just the routine care of the unit. GCS, vital signs and oxygen saturation were measured similarly in intervention and control groups. At the time of medical round, the intervention was paused, then continued after the clinical round was finished. The data was collected over three months (from March 2022 to May 2022).

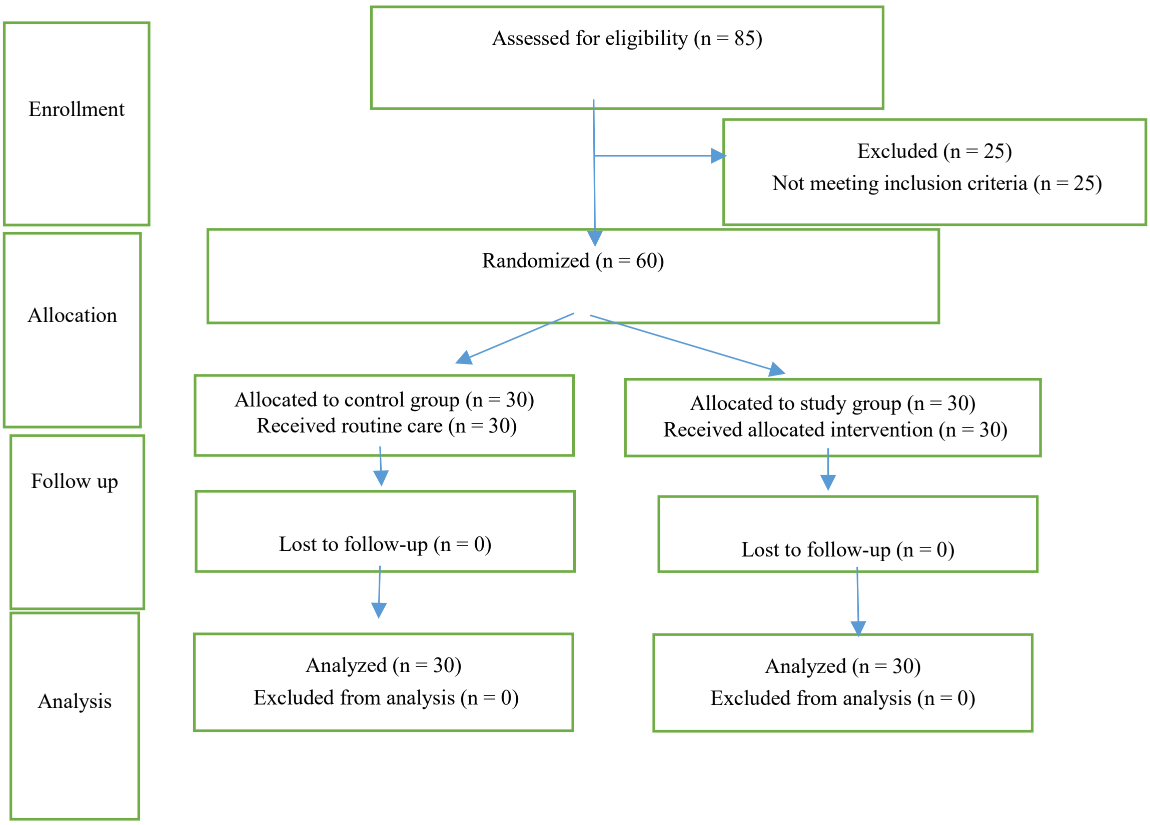

Figure 1-Flow Chart of Sampling Process

Ethical Considerations

A primary approval was obtained from the Research Ethical Committee, Faculty of Nursing, Cairo University, an official permission was obtained from the Manager of the selected hospitals to precede the study. Participation in this study was voluntary; each patient has the right to withdraw from the study at any time. An oral description of the study was clarified to the patient's relatives and written consents were obtained from them. Confidentiality and anonymity of each patient were assured through coding of all data.

Statistical analysis

Data entry and statistical analysis was done using SPSS 26 statistical software package. Data were presented using descriptive statistics in the form of frequencies and percentages for qualitative variables, and means and standard deviations, Chi-square, T- Test were used for compares the actual difference between parametric and nonparametric data. Repeated-measures analysis of variance was used to compare hemodynamic parameters (the patient's vital signs (systolic blood pressure (SBP), diastolic blood pressure (DBP), respiratory rate (RR), pulse rate (PR)), oxygen saturation (SaO2), and GCS) immediately before, after one hour, and three hours after the intervention.

Results:

Table (1): shows that, there is no significant difference between the initial characteristics of the study and control groups. The mean age of the patients was (46.4 ±11.1 years) in the study group and (47.5± 12.6 years) in the control group, regarding the gender (70%) were male and (30%) were female in the both group. The cause of admission was disturbed conscious level (30%) in the study group and (20%) in the control group. As regards to the medical diagnosis (50%)

was stroke in the study group and 50% in the control group.

Table (2) : reveals that, the mean Glasgow Coma Scale of the study group is significantly less than the mean GCS of the control group at all times of day 1 and day 2 and also before intervention and after 1 hour on day 3 and before intervention on day 4. The mean of the study group was improved at the last days than the first days, there is a significant difference within times of each group.

Table (3): clarifies that, the mean temperature of the study group is significantly less than the mean of the control group after 3 hours on day 4.

Table (4): shows that, the mean pulse of the study group is significantly higher than the mean of the control group before intervention and after 1 hour at day 3 and before intervention at day 4. There is a significant difference within times of each group.

Table (5): reveals that, the mean respiratory rate of the study group is significantly higher than the mean of the control group before intervention and after 3 hours on day 3. There is a significant difference within times of study group.

Table (6): indicates that, there is no significant difference between mean systolic blood pressure of study and control groups at any time. There is a significant difference within times of control group.

Table (7): shows that, there is no significant difference between mean diastolic blood pressure of study and control groups at any time. There is a significant difference within times of each group.

Table (8): reveals that, the mean of the oxygen saturation of the study group is significantly higher than the mean of the control group after 3 hours on day 1 and after 1 hour on day 2 and before intervention, and after 1 hour on day 3, and also after 3 hours on day 4 and at all times at day 5 as well as before intervention at day 6 and after 1 hour and 3 hours on day 7. There is a significant overall difference between the two groups and a significant overall difference within times of the study group.

Table (9): shows that, there is a significant correlation between gender and GCS and also between comorbidities and blood pressure.

Table (10): indicates that, the mean systolic and diastolic BP of atherosclerosis is the lowest and the mean systolic and diastolic BP of cerebrovascular stroke & hypertension is the highest.

Table (1): Frequency Distribution of the Studied Sample as Regards to Demographic and Medical Data.

Demographic Data & Medical Data.	Study group N=30		Control group N=30		Chi-square	p-value
	No.	%	No.	%		
Gender						
Male	21	70.0	21	70.0		0.99
Female	9	30.0	9	30.0	0.0	
Age (Years)						
20-30	1	3.3	5	16.7		
31-40	11	36.7	4	13.3		
41-50	6	20.0	7	23.3		
51-60	8	26.7	9	30.0		0.18
61-70	4	13.3	5	16.7	6.1	
Mean ± SD	46.4 ±11.1		47.5± 12.6		t=0.35	0.32
Medical Diagnosis						
Intracranial Hemorrhage	11	36.7	11	36.7		
Stroke	15	50.0	15	50.0		
Hydrocephles	0	0.0	1	3.3		
Subdural Hemorrhage	4	13.3	3	10.0	1.14	0.76
Cause of Admission						
Fall	0	0.0	1	3.3		
Right Side Weakness	5	16.7	1	3.3		
Left Side Weakness	2	6.7	2	6.7		
Disturbed conscious level	9	30.0	6	20.0		
Blurred Vision And Slurred Speech	3	10.0	3	10.0		
Accident	0	0.0	1	3.3		
Dysarthria, Left Side Weakness	0	0.0	1	3.3		
Seizure	1	3.3	1	3.3		
Fever And Headache	1	3.3	1	3.3		
A Aphasia And LSW	2	6.7	1	3.3		

Weakness, Numbness, Headache	1	3.3	2	6.7		
Headache, Blurred, Hypertension	2	6.7	1	3.3		
Right Side Weakness, Ataxia, Blurred Vision	3	10.0	4	13.3		
Seizure, Numbness	2	6.7	1	3.3		
Confusion, Dizziness, Fall	1	3.3	0	0.0		
Left Side Weakness, Disturbed conscious level	1	3.3	1	3.3	14.7	0.47
Comorbidities						
No	9	30.0	10	33.3		
Diabetes mellitus & Hypertension	5	16.7	5	16.7		
Atherosclerosis	0	0.0	1	3.3		
Hypertension	9	30.0	9	30.0		
Diabetes mellitus	2	6.7	5	16.7		
Liver Disease	1	3.3	0	0.0		
Renal Disorder	1	3.3	0	0.0		
Hypertension, Angina	2	6.7	0	0.0		
Cerebrovascular stroke & Hypertension	1	3.3	0	0.0	7.3	0.5

Table (2): Comparison between the Study and Control Groups as Regards to Glasgow Coma Scale:

Time		**Groups**		**t**	**p-value**
		Study group	Control group		
		Mean ± SD	**Mean ± SD**		
Day 1	Immediate before intervention	8.90±1.54	10.53±1.33	4.395	.000*
	After 1 hour	8.93±1.51	10.53±1.33	4.357	.000*
	After 3 hours	8.93±1.51	10.57±1.36	4.412	.000*
Day 2	Immediate before intervention	8.90±1.45	10.50±1.43	4.305	.000*
	After 1 hour	9.03±1.52	10.20±1.35	3.144	.003*
	After 3 hours	9.07±1.57	10.13±1.25	2.904	.005*
Day 3	Immediate before intervention	9.03±1.73	9.97±1.25	2.397	.020*
	After 1 hour	9.10±1.58	10.00±1.34	2.377	.021*
	After 3 hours	9.37±1.59	9.97±1.25	1.630	.109
Day 4	Immediate before intervention	9.20±1.54	9.97±1.30	2.084	.042*
	After 1 hour	9.20±1.71	9.80±1.24	1.555	.125
	After 3 hours	9.27±1.66	9.80±1.21	1.420	.161
Day 5	Immediate before intervention	9.27±1.62	9.73±1.23	1.258	.213
	After 1 hour	9.33±1.65	9.67±1.42	0.839	.405
	After 3 hours	9.43±1.76	9.67±1.42	0.566	.574
Day 6	Immediate before intervention	9.37±1.65	9.60±1.35	0.598	.552
	After 1 hour	9.30±1.74	9.40±1.33	0.249	.804
	After 3 hours	9.50±1.53	9.40±1.50	0.239	.812
Day 7	Immediate before intervention	9.53±1.68	9.40±1.50	0.324	.747
	After 1 hour	9.63±1.67	9.40±1.50	0.569	.571
	After 3 hours	9.67±1.69	10.30±5.26	0.628	.532
Within group differences		0.0001*	0.0001*		
Between group differences		0.06			

*Significant at p-value<0.05

Table (3): Comparison between the Study and Control Groups as Regards to Temperature:

Time		Groups		t	p-value
		Study group	Control group		
		Mean ± SD	**Mean ± SD**		
Day 1	Immediate before intervention	37.32 ±0.49	36.50 ±5.02	0.886	.379
	After 1 hour	37.16 ±0.54	37.35 ±0.44	1.460	.150
	After 3 hours	37.24 ±0.52	37.35 ±0.44	0.857	.395
Day 2	Immediate before intervention	37.27 ±0.51	37.29 ±0.32	0.182	.856
	After 1 hour	37.26 ±0.41	37.22 ±0.37	0.430	.669
	After 3 hours	37.31 ±0.56	36.16 ±5.46	1.147	.256
Day 3	Immediate before intervention	37.05 ±0.28	37.14 ±0.24	1.244	.219
	After 1 hour	36.99 ±0.33	37.10 ±0.42	1.129	.264
	After 3 hours	36.98 ±0.33	37.07 ±0.29	1.166	.248
Day 4	Immediate before intervention	37.08 ±0.46	37.23 ±0.41	1.348	.183
	After 1 hour	37.03 ± 0.41	37.19 ±0.40	1.483	.144
	After 3 hours	37.02 ±0.26	37.21 ±0.41	2.114	.039*
Day 5	Immediate before intervention	37.05 ±0.21	37.13 ±0.31	1.244	.219
	After 1 hour	36.99 ±0.23	37.06 ±0.27	1.093	.279
	After 3 hours	36.99 ±0.21	37.03 ±0.32	0.576	.567
Day 6	Immediate before intervention	37.04 ±0.35	37.05 ±0.33	0.114	.910
	After 1 hour	37.07 ±0.36	37.10 ±0.25	0.377	.708
	After 3 hours	37.10 ±0.38	37.08 ±0.22	0.167	.868
Day 7	Immediate before intervention	37.15 ±0.41	37.17 ±0.33	0.243	.809
	After 1 hour	37.12 ±0.35	37.14 ±0.33	0.226	.823
	After 3 hours	39.19 ±11.49	37.12 ±0.35	0.985	.329
Within group differences		0.49	0.68		
Between group differences		0.33			

*Significant at p-value<0.05

Table (4): Comparison between the Study and Control Groups as Regards to Pulse:

Time		Groups		t	p-value
		Study group	Control group		
		Mean ± SD	**Mean ± SD**		
Day 1	Immediate before intervention	88.23±14.07	86.00 ±7.81	0.760	.450
	After 1 hour	89.17±11.93	86.20 ±7.27	1.163	.250
	After 3 hours	90.23±11.38	86.47 ±9.56	1.388	.170
Day 2	Immediate before intervention	88.20±8.65	85.03 ±8.09	1.465	.148
	After 1 hour	87.40±8.89	84.47 ±7.54	1.378	.174
	After 3 hours	87.33±8.05	84.77 ±7.71	1.261	.212
Day 3	Immediate before intervention	87.77±6.91	82.87 ±7.09	2.711	.009*
	After 1 hour	87.77±7.78	83.53 ±7.88	2.093	.041*
	After 3 hours	86.57±7.00	83.37 ±7.29	1.735	.088
Day 4	Immediate before intervention	86.13±7.45	82.10 ±8.04	2.016	.048*
	After 1 hour	84.20±7.17	82.03 ±7.42	1.151	.255
	After 3 hours	85.50±6.85	82.00 ±7.09	1.945	.057
Day 5	Immediate before intervention	84.83±7.82	83.37 ±7.55	0.739	.463
	After 1 hour	85.47±7.07	82.43 ±8.44	1.509	.137
	After 3 hours	85.40 ±6.58	83.13 ±6.54	1.339	.186
Day 6	Immediate before intervention	85.23 ±8.68	82.57 ±6.73	1.330	.189
	After 1 hour	84.37 ±7.96	82.50 ±6.53	0.993	.325
	After 3 hours	84.17 ±8.41	83.03 ±6.95	0.569	.571
Day 7	Immediate before intervention	81.67 ±15.99	83.30 ±7.13	0.511	.611
	After 1 hour	84.77 ±6.64	83.50 ±7.54	0.691	.493
	After 3 hours	84.17 ±7.17	83.30 ±7.15	0.469	.641
Within group differences		0.0001*	0.0001*		
Between group differences		0.13			

*Significant at p-value<0.05

Table (5): Comparison between the Study and Control Groups as Regards to Respiratory Rate:

Time		**Groups**		**t**	**p-value**
		Study group	Control group		
		Mean ± SD	**Mean ± SD**		
Day 1	Immediate before intervention	19.00±2.57	19.00±2.27	0.000	1.000
	After 1 hour	19.57±2.16	18.87±1.72	1.389	.170
	After 3 hours	19.40±1.67	18.73±1.76	1.503	.138
Day 2	Immediate before intervention	19.13±1.41	18.47±1.68	1.668	.101
	After 1 hour	18.80±1.49	18.53±1.43	0.706	.483
	After 3 hours	19.07±1.31	18.47±1.57	1.607	.114
Day 3	Immediate before intervention	19.10±1.58	18.17±1.49	2.353	.022*
	After 1 hour	19.00±1.55	18.47±1.66	1.287	.203
	After 3 hours	19.57±1.96	18.30±1.58	2.757	.008*
Day 4	Immediate before intervention	19.03±1.56	18.30±1.53	1.833	.072
	After 1 hour	18.77±1.38	18.10±1.32	1.909	.061
	After 3 hours	18.77±1.65	18.63±1.56	0.321	.750
Day 5	Immediate before intervention	18.47±1.22	18.90±1.60	1.176	.244
	After 1 hour	18.27±1.26	18.87±1.20	1.894	.063
	After 3 hours	18.67±1.35	18.50±0.94	0.556	.580
Day 6	Immediate before intervention	18.73±1.66	18.67±1.30	0.173	.863
	After 1 hour	18.60±1.77	18.23±1.25	0.925	.359
	After 3 hours	18.33±2.02	18.43±1.63	0.210	.834
Day 7	Immediate before intervention	18.37±1.90	18.40±1.35	0.077	.938
	After 1 hour	18.57±1.85	18.37±1.45	0.466	.643
	After 3 hours	18.50±1.33	22.37±22.26	0.950	.346
Within group differences		0.01*	0.56		
Between group differences		0.63			

*Significant at p-value<0.05

Table (6): Comparison between the Study and Control Groups as Regards to Systolic Blood Pressure:

Time		Groups		t	p-value
		Study group	Control group		
		Mean ± SD	**Mean ± SD**		
Day 1	Immediate before intervention	139.67±27.85	133.00±21.52	1.037	.304
	After 1 hour	139.33±28.28	130.33±21.89	1.378	.173
	After 3 hours	140.00±26.65	130.5022.60	1.489	.142
Day 2	Immediate before intervention	138.67±26.88	129.00±23.98	1.470	.147
	After 1 hour	137.33±23.63	128.67±23.89	1.413	.163
	After 3 hours	136.33±22.97	127.33±22.58	1.530	.131
Day 3	Immediate before intervention	135.00±22.24	127.33±23.77	1.290	.202
	After 1 hour	132.33±23.00	126.67±27.21	0.871	.387
	After 3 hours	131.83±23.58	123.67±22.97	1.359	.179
Day 4	Immediate before intervention	131.17±20.91	123.33±22.49	1.397	.168
	After 1 hour	128.00±19.90	124.00±23.43	0.713	.479
	After 3 hours	130.17±17.83	124.67±22.09	1.061	.293
Day 5	Immediate before intervention	131.83±17.74	124.67±23.89	1.319	.192
	After 1 hour	129.00±17.68	127.00±25.62	0.352	.726
	After 3 hours	125.00±18.34	127.17±24.13	0.391	.697
Day 6	Immediate before intervention	130.00±21.66	127.00±24.52	0.502	.617
	After 1 hour	128.67±18.71	125.67±24.02	0.539	.591
	After 3 hours	161.67±179.68	124.67±20.97	1.120	.267
Day 7	Immediate before intervention	125.00±12.25	125.67±25.01	0.130	.896
	After 1 hour	126.00±13.80	120.50±30.64	0.897	.374
	After 3 hours	122.00±15.18	121.00±23.54	0.195	.846
Within group differences		0.26	0.001*		
Between group differences		0.16			

*Significant at p-value<0.05

Table (7): Comparison between the Study and Control Groups as Regards to Diastolic Blood Pressure:

Time		Groups		t	p-value
		Study group	Control group		
		Mean ± SD	**Mean ± SD**		
Day 1	Immediate before intervention	83.33±17.29	80.67±12.02	0.694	.491
	After 1 hour	82.33±14.55	80.33±11.59	0.589	.558
	After 3 hours	81.67±13.92	78.83±11.27	0.867	.390
Day 2	Immediate before intervention	80.00±12.87	77.83±11.87	0.678	.500
	After 1 hour	79.67±11.59	76.67±10.28	1.060	.293
	After 3 hours	79.67±10.98	77.33±11.43	0.806	.423
Day 3	Immediate before intervention	80.00±11.74	77.50±14.07	0.747	.458
	After 1 hour	77.00±10.88	78.67±14.79	0.497	.621
	After 3 hours	77.67±10.73	76.00±13.54	0.528	.599
Day 4	Immediate before intervention	79.33±11.43	76.67±12.13	0.876	.384
	After 1 hour	77.33±10.15	76.67±13.22	0.219	.827
	After 3 hours	77.67±10.40	76.17±12.15	0.514	.609
Day 5	Immediate before intervention	79.33±10.48	79.17±14.86	0.055	.960
	After 1 hour	77.67±10.40	79.33±12.30	0.567	.573
	After 3 hours	75.00±10.75	77.17±12.01	0.736	.465
Day 6	Immediate before intervention	80.00±12.59	74.50±12.89	1.672	.100
	After 1 hour	76.83±9.14	75.67±12.51	0.412	.682
	After 3 hours	77.00±7.94	76.83±11.18	0.063	.947
Day 7	Immediate before intervention	78.33±7.47	78.00±12.70	0.122	.902
	After 1 hour	75.67±7.28	74.00±11.92	0.653	.516
	After 3 hours	74.67±8.19	75.33±11.96	0.251	.802
Within group differences		0.002*	0.002*		
Between group differences		0.59			

Table (8): Comparison between the Study and Control Groups as Regards to Oxygen Saturation:

Time		Groups		t	p-value
		Study group	Control group		
		Mean ± SD	**Mean ± SD**		
Day 1	Immediate before intervention	93.57±7.13	94.10±1.30	0.404	.688
	After 1 hour	94.83±3.07	94.07±1.23	1.268	.210
	After 3 hours	95.40±1.52	94.07±1.14	3.837	.000*
Day 2	Immediate before intervention	94.90±4.85	94.27±1.17	0.695	.490
	After 1 hour	95.40±3.06	94.20±1.10	2.023	.048*
	After 3 hours	95.47±3.08	94.40±1.48	1.710	.093
Day 3	Immediate before intervention	96.27±1.31	94.50±1.31	5.228	.000*
	After 1 hour	95.80±1.90	94.27±1.57	3.403	.001*
	After 3 hours	95.20±3.26	93.93±2.74	1.628	.109
Day 4	Immediate before intervention	95.40±3.34	94.33±1.73	1.554	.126
	After 1 hour	95.20±4.91	94.57±1.36	0.681	.498
	After 3 hours	95.83±1.78	94.60±1.40	2.977	.004*
Day 5	Immediate before intervention	96.17±1.97	94.67±1.73	3.138	.003*
	After 1 hour	95.97±3.27	94.63±1.45	2.039	.046*
	After 3 hours	96.00±2.27	94.50±1.59	2.959	.004*
Day 6	Immediate before intervention	96.43±1.57	94.33±1.97	4.566	.000*
	After 1 hour	95.80±3.45	94.53±2.08	1.723	.090
	After 3 hours	95.70±5.09	94.30±2.26	1.376	.174
Day 7	Immediate before intervention	95.77±5.35	94.20±2.41	1.463	.149
	After 1 hour	96.23±3.80	94.47±2.34	2.166	.034*
	After 3 hours	96.43±3.85	94.40±2.31	2.481	.016*
Within group differences		0.001*	0.5		
Between group differences		0.03*			

*Significant at p-value<0.05

Table (9): Correlation between Selected Demographic, Medical Data and Hemodynamic Parameters of the Studied Sample:

Variables	Gender		Age		diagnosis		Cause of admission		Comorbidities	
	ANOVA test	**p-value**	**ANOVA test**	**p-value**	**ANOVA test**	**p-value**	**ANOVA test**	**p-value**	**ANOVA test**	**p-value**
GCS	3.03	.08	1.41	.17	.09	.96	1.70	.09	.84	.66
Temperature	.487	.488	1.161	.338	.286	.835	.379	.978	.111	.999
Pulse	1.227	.273	.214	.930	.718	.545	1.233	.285	.476	.867
Respiratory rate	.273	.603	1.845	.133	1.525	.218	1.266	.264	.819	.589
Systolic BP	2.187	.145	2.331	.067	2.837	.05	1.421	.180	4.055	.001*
Diastolic BP	.400	.530	2.506	.052	2.268	.091	1.724	.081	2.959	.008*
Oxygen Saturation	.572	.452	1.763	.149	.082	.970	.992	.480	.222	.985

*Significant at p-value<0.05

Table (10): Comparison between Blood Pressure and Comorbidities of the Studied Sample:

Items	Systolic BP	Diastolic BP
	Mean ± SD	**Mean ± SD**
Comorbidities		
No	118.65±17.63	72.74 ± 8.68
Diabetes Millets & Hypertension	139.07±21.14	81.00±11.37
Atherosclerosis	**107.14± 0.1**	**68.10**±0.1
Hypertension	140.66±12.61	83.49±5.49
Diabetes Millets	117.07±14.19	73.40±8.38
Liver Disease	120.95±0.1	76.19±0.1
Renal Disorder	111.90±0.1	70.00±0.1
Hypertension & Angina	150.00±6.73	83.33±1.35
Cerebrovascular Stroke & Hypertension	**150.48±0.1**	**86.67**±0.1

Discussion

The current study investigated the clinical effects of serial foot warm bath and massage in TBI by means of a randomized, controlled trial. Overall, the treatment program was well accepted and the patients neither had worsened nor exhibited an obvious improvement of clinical symptoms during partial hydrotherapy application.

According to the findings of the current study, no significant differences were observed between intervention and control groups in relation to demographic variables, this finding is in concordance with **Parker, Higgins, Mlombile, Mohr, & Wagner, (2018)** who investigated the effects of warm water immersion on blood pressure, heart rate and heart rate variability in people with chronic fatigue syndrome, and found that there were no differences between participants in the control and study group, in terms of age, gender, height, weight, and BMI.

The findings of the current study demonstrated that, there is no significant difference between mean pulse, systolic and diastolic blood pressure of the study and control groups. These findings are consistent with **Son & Yoo, (2016)** studied effects of a footbath program on heart rate variability, blood pressure, body temperature and fatigue in stroke patients and indicated that, no significant differences in diastolic blood pressure, core temperatures, forehead temperatures, and hand temperatures between the two groups. Moreover, **Vahedian-Azimi et al. (2014),** examined the effects of massage by patients' families on the vital signs of patients in the general ICU, and mentioned that, no significant difference in heart rate between the intervention and control groups. However, some other studies contradicted the previous findings, for example, **da Silva et al. (2017)** illustrated that Swedish foot massage for 30 minutes reduces vital signs (heart rate, respiratory rate, systolic arterial pressure, diastolic arterial pressure, and mean arterial pressure) immediately after the massage, with significantly decreased heart rate 30 minutes after massage compared to before it.

The current study revealed that, the mean temperature of the study group is significantly less than the mean of the control group after 3 hours on day 4 while the mean of oxygen saturation of the study group is significantly higher than the mean of the control group. These findings are in the same line with, **Park et al. (2018)** reported that, foot bathing significantly helped in regulating skin temperature and oxygen saturation in all 3 groups of their study.

Regarding the effect of warm footbath and massage on the GCS among patients with traumatic brain injury, the current study showed the mean of the study group was improved on the last days than the first days, and there is a significant difference within times of each group, The same findings were stated by **Yekeh Fallah et al. (2018)** who studied tactile stimulation improves consciousness and vital signs in patients with traumatic brain, and documented that the mean consciousness level of subjects in the intervention group was significantly higher than in the control group after warm foot bath tactile stimulation increased the level of consciousness and improved vital signs in patients with severe TBI. However, the results of another study revealed that full body massage therapy increases the level of consciousness **(Paker et al., 2018).**

From the researcher's point of view, the difference between the findings of the current study and some other studies might be due to differences in the study population, setting capabilities, participant level of consciousness, duration and surface area of warm footbath and massage application. In this regards, **Michalsen et al. (2003)** assumed that the useful effects of thermal hydrotherapy applications need to be applied continuously by the patient for sustained benefits. Therefore, the long-term effects of hydrotherapy may be compromised by decreasing adherence. Thus, the assessment of long-term adherence remains critical in future studies with hydrotherapy.

Conclusion: warm foot bath & massage can improve the GCS, respiratory rate, and oxygen saturation among patients with traumatic brain injury for the study group.

Recommendations: Based upon the findings of the study, the following are recommended:

1-Applying the warm foot bath & massage for patients with traumatic brain injury.

2-Replication of the same study on larger probability samples at different geographical locations for data generalization.

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